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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,786	09/28/2005	Kang Ting	38586-327005	9987

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	**PAPER NUMBER**
1635	

MAIL DATE	DELIVERY MODE
07/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,786	TING, KANG	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *1-40 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41 and 43-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

An amendment was received and entered on 5/18/07.

Claims 42-54 were added as requested.

Newly submitted claim 42 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: it is drawn to an agent that alters expression or activity of a Nell-1 protein, restricted to group 19 of the restriction requirement of 1/9/07. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 42 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-40 and 42 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/25/07.

Claims 1-54 are pending.

Claims 41 and 43-54 are under consideration.

Rejections and objections not reiterated in this action are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41 and 43-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 41 and 43-54 are drawn to compositions comprising a Nell-1 protein. The specification as filed discloses a single example of a Nell-1 nucleic acid isolated from homo sapiens. No alleles of this nucleic acid are disclosed, no homologs or orthologs from any other species are disclosed, and no amino acid sequence of any Nell-1 protein is disclosed. While one of skill in the art can determine the Nell-1 amino acid sequence from the nucleic acid sequence of the disclosed allele, this would not lead one to the amino acid sequence of any other Nell-1 allele, homologue, or ortholog. Thus one of skill in the art could not conclude that Applicant was in possession of the claimed genus embracing Nell-1 polypeptides from any source at the time the invention was filed.

Response to Arguments

Applicant's arguments filed 5/18/07 have been fully considered but they are not persuasive.

Applicant addresses the rejection at pages 8 and 9 of the response. Applicant indicates that the claimed NELL-1 protein includes any protein expressed by any NELL-1 nucleic acid sequence which were documented and known to ordinary artisans. The

Office agrees that the claimed genus certainly includes any NELL-1 nucleic acid sequence which were documented and known to ordinary artisans, but points out that the claimed genus is not limited to known sequences, but instead embraces any NELL-1 protein. Applicant indicates that the claimed genus is adequately described by the disclosure at specification page 8 of NELL-1 cDNA and genomic DNA as described in Watanabe (1996), Ting (1999), and GenBank U57523. Applicant relies for support on MPEP 2163. However, MPEP 2163 indicates that the written description requirement for genus claims may be met through disclosure of a representative number of species. This supports the instant rejection, and not Applicant's argument. The specification as filed discloses by structure or relevant identifying characteristic only a single species of the claimed NELL-1 polypeptide. Applicant has not shown otherwise. This disclosure would not convey to one of skill in the art that Applicant was in possession of any variant, allele, homolog, or ortholog of NELL-1 other than the disclosed sequence. However, the claims embrace any NELL-1 polypeptide from any organism, as well as alleles and variants of those polypeptides. The courts have found that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated. Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). This would apply to polypeptides as well. The instant application does not provide a written description that would allow one of skill in the art to immediately envisage the specific structure for NELL-1 protein sequences other than the single species disclosed. *Vas-Cath Inc. v. Mahurkar*,

19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed* (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

Applicant also relies on the findings of the court in *Falkner v. Inglis* quoting the court as holding that "the Board erred in holding that the specification do [sic] not meet the written description requirement because they do [sic] not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes" and further adding the qualifier "where the genes involved known DNA segments". This is unpersuasive because the instant claims are drawn to a tremendous number of unknown protein sequences, and the specification discloses only one known sequence. Further the specification as filed provides no guidance as to what structural features are required by the members of the claimed genus, so no representative number of species is disclosed by either structure or relevant identifying characteristic. Accordingly the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41 and 43-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Ting (WO 01/24821).

Ting taught a composition comprising a pharmaceutically acceptable excipient and a Nell-1 protein. See page 36, lines 9-20. Preferred delivery vehicles are porous (see page 38, lines 19 and 20). Other delivery vehicles comprise a composition to render Nell-1 resistant to acidic and enzymatic hydrolysis such as a liposome (page 37, lines 2-4). Dosage forms for oral administration comprising other encapsulating carriers are contemplated at page 36, lines 31 and 32. Dosages are in the range of 2-8 mg/ml (see page 37, lines 24-27). Ting contemplated bone graft material comprising Nell-1 at page 39, line 5, as well as bone graft materials comprising bone morphogenic proteins, cell adhesion molecules, reconstituted collagen, demineralized bone matrix, mineralized bone matrix, polymers, ceramics, and bioglass (see page 39, lines 12-16; and page 40, lines 4-23).

Thus Ting anticipates the claims.

Response to Arguments

Applicant's arguments filed 5/18/07 have been fully considered but they are not persuasive.

Applicant addresses the rejection at pages 9 and 10 of the response. Applicant argues that Ting describes compositions comprising Nell-1 and intended for the purpose of affecting bone mineralization, but does not describe compositions with Nell-1 in an

effective amount for increasing osteoblast differentiation. Applicant notes that these two compositions may not be the same thing. This is unpersuasive. The instant specification at page 44, lines 6-10 indicates that the dosage of Nell-1 is in the range of from about 1 to about 10000 microgram. The specification of Ting indicates the exact same range at page 37, lines 31-33. Absent evidence to the contrary, this range of Nell-1 causes osteoblast differentiation. Applicant has not pointed to any evidence in the specification as filed that indicates that formulations comprising an amount of Nell-1 in this range would not have the functional effect required by the claims. The office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989). Applicant has not met this burden, so the rejection is maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.
Primary Examiner
Art Unit 1635